Ayala Pharmaceuticals Reports Second Quarter 2021 Financial Results and Provides Business Update

August 13, 2021

- Enrolled the First Patient in the Phase 2/3 Pivotal Trial of AL102 for the Treatment of Desmoid Tumors

- Multiple Near-Term Milestones Across Clinical-Stage Pipeline

- Updated ACCURACY Trial Data to Be Presented at ESMO 2021-

REHOVOT, Israel and WILMINGTON, Del., Aug. 13, 2021 (GLOBE NEWSWIRE) -- Ayala Pharmaceuticals, Inc. (Nasdaq: AYLA), a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, primarily in genetically defined patient populations, today reported financial results for the period ended June 30, 2021 and highlighted recent progress and upcoming milestones for its pipeline programs.

“Ayala is well positioned for strong clinical progress throughout the remainder of this year. In the second quarter, we continued to advance our pipeline programs and we are gearing up for a data readout from AL101 in our ACCURACY trial in adenoid cystic carcinoma at the upcoming ESMO meeting in September, while also advancing our AL102 clinical trials in desmoid tumors and multiple myeloma,” said Roni Mamluk, Ph.D., Chief Executive Officer of Ayala. “Our science is deeply rooted in the promise of predicting, identifying and addressing tumorigenic drivers of cancer and we continue to see value in our approach combining bioinformatics and next-generation sequencing. There remains a significant unmet need among patients with genetically defined cancers and we believe that our pipeline has the potential to address the ongoing shortfalls of existing therapies.”

Recent Business Highlights and Upcoming Milestones:

- **Enrolled First Patient in the Phase 2/3 RINGSIDE Trial of AL102 for the Treatment of Desmoid Tumors:** Ayala recently enrolled the first patient in its pivotal Phase 2/3 RINGSIDE trial of AL102 for the treatment of desmoid tumors with multiple sites open in the U.S. and globally**.** Ayala expects to report an initial interim data read-out from part A of the trial in mid-2022, with part B of the study commencing thereafter.
- **Dosed First Patient in the Phase 1 Trial of AL102 in Combination with Novartis’ BCMA Targeting Agent, WVT087 for the Treatment of Relapsed/Refractory Multiple Myeloma:** In April 2021, Ayala announced the dosing of the first patient in the Phase 1 combination trial of AL102 with Novartis’ investigational anti-B-cell maturation antigen (BCMA) agent, WVT078, for the treatment of relapsed and/or refractory (R/R) multiple myeloma (MM).
- **Phase 2 TENACITY Trial of AL101 for the Treatment of Triple Negative Breast Cancer Continues to Progress:** Ayala continues to enroll patients in the Phase 2 TENACITY clinical trial of its potent, selective small molecule gamma secretase inhibitor (GSI), AL101, for the treatment of patients with Notch-activated recurrent or metastatic (R/M) triple negative breast cancer (TNBC). The Company expects to report preliminary data from this ongoing trial in 2022.
- **On Track to Report Additional ACCURACY Phase 2 Data; Patient Enrollment in 6mg Cohort of Phase 2 ACCURACY Study Completed:** Ayala completed enrollment of patients in the 6mg cohort of the Phase 2 ACCURACY study of AL101 for the treatment of R/M adenoid cystic carcinoma (ACC), which includes 42 subjects. Further trial progress updates, including additional data, will be presented at the upcoming European Society for Medical Oncology (ESMO) 2021 Congress being held virtually September 16-21, 2021.

Second Quarter 2021 Financial Results

- **Cash Position:** Cash and cash equivalents were $44.4 million as of June 30, 2021, as compared to $42.0 million as of December 31, 2020.
- **Collaboration Revenue:** Collaboration revenue was $0.8 million for the second quarter of 2021, as compared to $1.0 million for the same period in 2020.
- **R&D Expenses:** Research and development expenses were $8.1 million for the second quarter of 2021, compared to $5.1 million for the same period in 2020. The increase was primarily driven by the advancement of Ayala’s clinical programs.
- **G&A Expenses:** General and administrative expenses were $2.5 million for the second quarter of 2021, compared to $1.5 million for the same period in 2020. The increase was primarily related to costs associated with becoming a public company.
- **Net Loss:** Net loss was $10.8 million for the second quarter of 2021, resulting in a basic and diluted net loss per share of $0.75 Net loss was $6.7 million for the same period in 2020, resulting in a basic and diluted net loss per share of $0.74.

About Ayala Pharmaceuticals

Ayala Pharmaceuticals, Inc. is a clinical-stage oncology company focused on developing and commercializing small molecule therapeutics for patients suffering from rare and aggressive cancers, primarily in genetically defined patient populations. Ayala's approach is focused on predicating, identifying and addressing tumorigenic drivers of cancer through a combination of its bioinformatics platform and next-generation sequencing to deliver targeted therapies to underserved patient populations. The company has two product candidates under development, AL101 and AL102, targeting the aberrant activation of the Notch pathway with gamma secretase inhibitors to treat a variety of tumors including Adenoid Cystic Carcinoma, Triple Negative Breast Cancer (TNBC), T-cell Acute Lymphoblastic Leukemia (T-ALL), Desmoid Tumors and Multiple Myeloma (MM) (in collaboration with Novartis). AL101, has received Fast Track Designation and Orphan Drug Designation from the U.S. FDA and is currently in a Phase 2 clinical trial for patients with ACC (ACCURACY) bearing Notch activating mutations and in a Phase 2 clinical trial for patients with TNBC (TENACITY) bearing Notch activating mutations and other gene rearrangements. AL102 is currently in a Pivotal Phase 2/3 clinical trials for patients with desmoid tumors (RINGSIDE) and is being evaluated in a Phase 1 clinical trial in combination with Novartis' BMCA targeting agent, WVT078, in Patients with relapsed/refractory Multiple Myeloma. For more information, visit www.ayalapharma.com.

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Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements relating to our development of AL101 and AL102, the promise and potential impact of our preclinical or clinical trial data, the timing of and plans to initiate additional clinical trials of AL101 and AL102, upcoming milestones, including without limitation the timing and results of any clinical trials or readouts, patient enrollment and the sufficiency of cash to fund operations. These forward-looking statements are based on management's current expectations. The words "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the impact of the COVID-19 pandemic on our operations, including our preclinical studies and clinical trials, and the continuity of our business; we have incurred significant losses, are not currently profitable and may never become profitable; our need for additional funding; our cash runway; our limited operating history and the prospects for our future viability; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in regulatory approval; our requirement to pay significant payments under product candidate licenses; the approach we are taking to discover and develop product candidates and whether it will lead to marketable products; the expense, time-consuming nature and uncertainty of clinical trials; enrollment and retention of patients; potential side effects of our product candidates; our ability to develop or to collaborate with others to develop appropriate diagnostic tests; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; risks associated with international operations; our ability to retain key personnel and to manage our growth; the potential volatility of our common stock; costs and resources of operating as a public company; unfavorable or no analyst research or reports; and securities class action litigation against us. These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the U.S. Securities and Exchange Commission (SEC) on March 24, 2021 and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. New risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

AYALA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands (except share and per share data)

	June 30 2021	December 31 2020
	(Unaudited)	
CURRENT ASSETS:		
Cash and Cash Equivalents	$ 44,412	$ 42,025
Short-term Restricted Bank Deposits	119	90
Trade Receivables	929	681
Prepaid Expenses and other Current Assets	1,550	1,444
Total Current Assets	47,010	44,240
LONG-TERM ASSETS:		
Other Assets	$ 270	$ 305
Property and Equipment, Net	1,192	1,283
Total Long-Term Assets	1,462	1,588
Total Assets	**$ 48,472**	**$ 45,828**

LIABILITIES AND STOCKHOLDERS' EQUITY:		
CURRENT LIABILITIES:		
Trade Payables	$ 2,833	$ 3,726
Other Accounts Payables	2,377	3,151
Total Current Liabilities	5,210	6,877
LONG TERM LIABILITIES:		
Long-term Rent Liability	502	553
Total Long-Term Liabilities	$ 502	$ 553
STOCKHOLDERS' STOCKHOLDERS' EQUITY:		
Common Stock of $0.01 par value per share; 200,000,000 shares authorized at June 30, 2021 and December 31,		
2020; 13,240,961 and 12,824,463 shares issued at June 30, 2021 and, respectively December 31, 2020; 13,092,925		
and 12,728,446 shares outstanding at June 30, 2021 and December 31, 2020, respectively	$ 131	$ 128
Additional Paid-in Capital	133,925	109,157
Accumulated Deficit	(91,296)	(70,887)
Total Stockholders' Equity	42,760	38,398
Total Liabilities and Stockholders' Equity	$ **48,472**	$ **45,828**

AYALA PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share & per share amounts)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenues from licensing agreement	$ 761	$ 1,045	$ 1,735	$ 2,046
Cost of services	(761)	(1,045)	(1,735)	(2,046)
Gross profit	—	—	—	—
Operating expenses:				
Research and development	8,121	5,067	15,046	10,195
General and administrative	2,536	1,546	4,839	2,857
Operating loss	(10,657)	(6,613)	(19,885)	(13,052)
Financial Income (Loss), net	(22)	40	(114)	2
Loss before income tax	(10,679)	(6,573)	(19,999)	(13,050)
Taxes on income	(162)	(139)	(410)	(260)
Net loss attributable to common stockholders	(10,841)	(6,712)	(20,409)	(13,310)
Net Loss per share attributable to common stockholders, basic and diluted	$ (0.75)	$ (0.74)	$ (1.46)	$ (1.90)
Weighted average common shares outstanding, basic and diluted	**14,417,423**	**9,018,637**	**13,954,676**	**6,989,762**